

REMARKS

The Examiner has rejected claims 1, 8-11, 37 and 49-53 under 35 U.S.C. §102 as being anticipated by Niederauer (WO 01/32072).

Applicant respectfully disagrees with this rejection, and asks the Examiner to withdraw the rejection, for at least the following reasons. If the Examiner deems the arguments below to be unpersuasive, and/or deems new claims 54-55 to be unpatentable, Applicant respectfully requests an explanation of the Examiner's reasoning and the courtesy of an interview to advance prosecution.

Both of Applicant's independent claims, claims 1 and 37, require a first component comprising a preformed ceramic scaffold structure and a second component comprising a polymer. The two components have different relative rates of *in vivo* degradation, with the first component having a higher rate of *in vivo* degradation than the second component. As discussed in Applicants' specification, because the first component has a higher rate of *in vivo* degradation than the second component, after implantation of the device the first component degrades *in vivo* leaving a scaffold formed of the second component (i.e., the initial ceramic scaffold degrades, leaving a polymeric scaffold). (See Applicant's specification, page 9, "Polymeric Scaffolds from Polymer/Ceramic Composites.") The resulting polymeric scaffold has pores into which tissue can infiltrate, whereas the device, when initially implanted, does not have sufficient porosity to support tissue ingrowth.

Niederauer discloses an implant that comprises a biodegradable polymer and a biodegradable ceramic. The ceramic is in the form of ceramic particles substantially uniformly distributed through the polymer. (Niederauer, e.g., page 6, paragraph 3, and page 8, second full paragraph.) *In vivo*, or under certain manufacturing conditions, the ceramic particles dissolve more rapidly than the polymer, leaving a porous polymeric structure. (Niederauer, page 10, first paragraph.)

The Examiner alleges that Niederauer discloses a preformed ceramic scaffold structure.

In Applicant's previous response, Applicant noted that there is no mention of a preformed ceramic scaffold in any of the passages cited by the Examiner in the Final Office Action, i.e.,

page 6, paragraph 5; page 4, paragraph 4; and page 11, paragraph 1. Page 6, paragraph 5 refers to an implant formed by mixing ceramic particles into a polymer. Page 4, paragraph 4 merely discusses biodegradable polymers. Page 11, paragraph 1 discusses bimodal degradation of the ceramic particles and polymer matrix discussed at page 6, paragraph 5.

In response, the Examiner explained in the Advisory Action that the Examiner is equating the polymer and the ceramic particles disclosed in Niederauer with Applicant's preformed ceramic scaffold. Thus, the Examiner equates the entire Niederauer implant with Applicant's preformed ceramic scaffold.

Assuming, for the sake of argument, that the entire Niederauer implant (polymer and dispersed ceramic particles) can properly be construed as a preformed ceramic scaffold, which Applicant does not concede, this interpretation would nonetheless only satisfy the first component recited in Applicant's claim. There is no teaching or suggestion in Niederauer of a second component, comprising a polymer, which has a lower rate of *in vivo* degradation than the first component (according to the Examiner's interpretation, the entire polymer/ceramic implant).

Niederauer cannot anticipate Applicant's claims because if the polymer and ceramic of Niederauer are considered to together constitute a preformed ceramic scaffold then Niederauer lacks Applicant's second component, while if Niederauer's polymer is equated with Applicant's second component Niederauer does not disclose a preformed ceramic scaffold but instead only ceramic particles.

Applicant wishes to note that dependent claim 52 recites that the polymer of the second component "fills interconnecting pores of the ceramic scaffold." If the polymer and ceramic of Niederauer are together considered to be the preformed ceramic scaffold, as contended by the Examiner, then Niederauer clearly does not disclose a polymer that fills interconnecting pores of this "scaffold." Moreover, there is no suggestion in Niederauer that the implant includes interconnecting pores, or in fact any pores until after the ceramic particles have dissolved.

Moreover, with respect to new claim 54, clearly Niederauer does not teach or remotely suggest a device in which pores of a preformed ceramic scaffold structure are infiltrated with a polymer.

Therefore, the Applicant submits that the rejected claims are patentable over Niederauer.

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No fees are believed to be due at this time. Please apply any other charges or credits, to
deposit account 06-1050, referencing Attorney Docket No. 00167-482001.

Respectfully submitted,

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